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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,546	10/14/2003	Sanford D. Altman	OAV-102	4948

23557 7590 03/23/2007
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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/685,546

Applicant(s)

ALTMAN, SANFORD D.

Examiner

Christopher D. Koharski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 9-16 and 18-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9-16 and 18-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Examiner acknowledges the RCE filed 12/11/2006, in which claim 1 was amended. Currently claims 1-4, 9-16 and 18-19 are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim Rejections - 35 USC § 103

Claims 1, 3 and 9-11 are rejected under 35 U.S.C 103(a) as being unpatentable over Schreck (4,411,655) in view of Prestidge et al. (2004/0193109). Schrek meets the claim limitations as described below except for the safety needle feature.

However, Schreck and Prestidge et al. teach apparatuses for piercing they body.

Regarding claims 1, 3 and 9-11, Schrek discloses a housing (6), catheter portion capable of securely transmitting fluids (4,7) which is composed of a shape memory alloy

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that is capable of attaining a change in shape after insertion into the body (based on temperature after introduction in the body) (see col 7), and a manually movable penetrating needle (3) (Figures 1-2).

Regarding claims 1, 3 and 9-11, Prestidge et al. discloses a needle (20) catheter system (60) that contains a safety feature that is formed by the catheter body (18) (Figures 1-2, and 19-20).

At the time of the invention, it would have been obvious to include the needle protection feature to avoid needle stick and increase medical safety with needle catheter devices. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Prestidge et al.

Claim Rejections - 35 USC § 103

Claims 2 and 4 are rejected under 35 U.S.C 103(a) as being unpatentable over Schreck (4,411,655) in view of Prestidge et al. (2004/0193109) in further view of Balbierz et al. (5,964,744). The modified Schreck meets the claim limitations as described above but does not include a plurality of openings and a polymeric shape memory alloy.

However, Balbierz et al. teaches a polymeric medical device with shape memory. Regarding claims 2 and 4, Balbierz et al. teaches a catheter system (800) that has a plurality of openings on the ends and in the catheter body (802) (Figures 1-12C), in

addition Balbierz et al. also teaches a catheter system that has a shape memory section that can attain different shapes in response to exposure to the body (Figures 12-12C).

At the time of the invention, it would have been obvious to incorporate the plurality of openings and shape memory shapes of Balbierz et al. with the modified system of Schreck because the addition of the openings allows for better distribution of better flow through the catheter and the different shapes allows for easier catheter positioning. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Balbierz et al.

Claim Rejections - 35 USC § 103

Claims 12-16 are rejected under 35 U.S.C 103(a) as being unpatentable over Schreck (4,411,655) in view of Prestidge et al. (2004/0193109) in further view of Weikel et al. Schreck meets the claim limitations as described above but does not include therapeutic agents or a hydrophilic coating.

However, Weikel et al. teaches an inflatable catheter device. Regarding claims 12-16, Weikel et al. teaches the use of distal end coatings on a catheter to increase the lubricity and provide protection against bacterial agents ([0007] and [0070]).

At the time of the invention, it would have been obvious to use coatings of Weikel et al. with the system of Schreck because the addition of the coating provides reduction in tissue damage during catheter placement in the body and the antibacterial element increases sterility. Both references are analogous in the art and with the instant

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invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Weikel et al.

Claim Rejections - 35 USC § 103

Claims 18 and 19 are rejected under 35 U.S.C 103(a) as being unpatentable Schreck (4,411,655) in view of Prestidge et al. (2004/0193109) in further view of Sharkey et al. Yoon meets the claim limitations as described above but does not include a transparent section for viewing and a portion with visible markers.

However, Sharkey et al. teaches a catheter device for treating intervertebral discs. Regarding claims 18 and 19, Sharkey et al. teaches the use of a catheter system with a sheath and catheter that has visible markings on the catheter that are visible through the transparent sheath (col 16, ln 40-53).

At the time of the invention, it would have been obvious to use visible markings and transparent sheath of Sharkey et al. with the system of Schreck et al. because the addition of the markings and transparent sheath to allow for the proper and very accurate placement of the catheter within the body during surgical intervention. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Sharkey et al.

Response to Arguments

Applicant's arguments filed 11/08/2006 have been fully considered but they are not persuasive. Applicant's representative asserts the Schreck does not disclose a catheter portion that is capable of securely transmitting fluids and only tubular

structures. Examiner disagrees, the catheter portion (4,7) of Schreck is capable of transmitting fluids, where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function, see *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Additionally, one of the disclosed shapes of Schreck is a helical spiral.

Applicant's arguments filed 11/08/2006 have been fully considered but they are not persuasive. Applicant's representative asserts that Schreck in view of Prestidge et al. does not disclose the safety feature as disclosed by Applicant. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the safety feature with a manual depressed button) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore the claim recitation only discloses a safety feature for an inadvertent needle stick formed by the catheter; therefore the references meet the claim limitations.

Suggested Allowable Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests the addition of structural/functional limitations drawn to the safety feature.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 2/6/07




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AU 3763